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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,557	01/21/2004	D. James Surmeier	Nwestern-08739	2838
72960	7590	11/13/2008	EXAMINER	
Casimir Jones, S.C. 440 Science Drive Suite 203 Madison, WI 53711			CHONG, KIMBERLY	
			ART UNIT	PAPER NUMBER
			1635	
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			11/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/761,557	Applicant(s) SURMEIER ET AL.	
	Examiner KIMBERLY CHONG	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-21, 24, 25 is/are rejected.
- 7) ☒ Claim(s) 22 and 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 08/06/2008 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 02/06/2008 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 08/06/2008, claims 18-25 are pending in the application.

Response to Declaration

The declaration filed on 08/06/2008 under 37 CFR 1.132 is not sufficient to overcome the rejection of claims 18-21 and 24-25 under 35 U.S.C. 103(a) as being unpatentable over Erisir et al. (J. Neurophysiology. 1999, Vol. 82: 2476-2489 cited on Applicant's IDS filed 11/23/2005), Baranauskas et al. (Journal of Neuroscience 1999, Vol. 10(15): 6394-6404 cited on Applicant's IDS filed 11/23/2005), Tkatch et al. (Society for Neuroscience, 1999, Vol. 25L Abstract 179.17), Weiser et al. (cited on Applicant's IDS filed 11/23/2005), Tuschl et al. (cited on PTO form 892 field 03/09/2007) and Low et al. (cited on PTO form 892 field 03/09/2007) for reasons explained herein.

Response to Applicant's Arguments

Claim Objections

Applicant has not addressed this objection and has made no claim amendments, therefore claims 22 and 23 remain objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and deleting non-elected subject matter.

Re: Claim Rejections - 35 USC § 103

The rejection of claims 18-21 and 24-25 under 35 U.S.C. 103(a) as being unpatentable over Erisir et al. (J. Neurophysiology. 1999, Vol. 82: 2476-2489 cited on Applicant's IDS filed 11/23/2005), Baranauskas et al. (Journal of Neuroscience 1999, Vol. 10(15): 6394-6404 cited on Applicant's IDS filed 11/23/2005), Tkatch et al. (Society for Neuroscience, 1999, Vol. 25L Abstract 179.17), Weiser et al. (cited on Applicant's IDS filed 11/23/2005), Tuschl et al. (cited on PTO form 892 field 03/09/2007) and Low et al. (cited on PTO form 892 field 03/09/2007) is maintained.

Applicant's arguments filed 08/06/2008 have been fully considered but they are not persuasive. Applicant argues the Examiner has not demonstrated the existence of a finite number of predictable solutions nor a reasonable expectation of success should the reference be combined. Applicants further submit the Kv3.4 subunit was surprisingly and unexpectedly discovered to be expressed in fast-spiking neurons but not in non fast-spiking neurons and argues there is no evidence in the cited art or the

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knowledge of one of skill in the art that would lead one to target Kv3.4 in order to decrease sustained high frequency discharge in a fast spiking neuronal cell. Further, Dr. Surmeier states in his declaration that it would not have been obvious to combine the teachings to arrive at the presently claimed invention because prior to the present invention, one would not have been able to predict that Kv3.4 subunits were important to the ability of neurons to spike at high frequencies and would not have been motivated to inhibit their activity.

With regard to Kv3.4 surprisingly discovered in fast-spiking neurons by Applicant in the present invention, the Tkatch et al. reference (which includes Dr. Surmeier as an author) tested non globus pallidus (GP) neurons for the presence of Kv3.4 mRNA and state these channels were not present. Based on Baranauskas et al., GP are considered fast spiking neurons and therefore it was known in the art that fast spiking neurons were known to express Kv3.4 channels as compared to non fast spiking neurons. Further, Tkatch et al. recognized the normal high frequency burst produced by GP neurons was increased in Parkinson's disease patients and noticed this increase in bursting is due to the broadening of action potentials and suggested the Kv3.4 channels may be responsible for such broadening.

As stated in the previous Office action, one would have been motivated to modulate the expression of a Kv3.4 gene given the suggestion by Tkatch regarding Kv3.4 and given Baranauskas et al. teach related potassium channels Kv3.1 and Kv3.2 are capable of sustained high frequency discharge in GP neuronal cells which have been indicated in Parkinson's disease. Further Baranauskas et al. suggests genetic

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manipulation that normalizes the ratio of potassium channels in cells would assist in suppressing unwanted high frequency activity from said channels.

With regard to Dr. Surmeier's declaration, one of skill would have been motivated to manipulate the expression of Kv3.4 to decrease the high frequency discharge from the potassium channel to further study the role Kv3.4 has in the emergence of Parkinson's disease in humans. One of skill in the art would have wanted to use the most efficient method of inhibiting gene expression from a gene and therefore would have been motivated to generate a siRNA targeted to a Kv3.4 gene as taught by Tuschl et al. and Weiser et al. At the time of filing of the instant invention, it was well known in the art regarding the advantages of studying the role certain genes play in diseases by silencing the expression from said genes and one would have clearly used a siRNA particularly given that Tuschl et al. teach determining or modulating, particularly inhibiting the function of a such a gene, provide valuable information and therapeutic benefits in the field of medicine (see page 8, lines 25- 28).

Dr. Surmeier's declaration suggests there was very little work on Kv3.4 subunits and the present invention showed that contrary to the prediction of the published literature that Kv3.4 subunits were not important to the ability of neurons to spike at high frequencies when in fact they were important. There is no subjective evidence e.g. a reference, presented with the declaration filed on 08/06/2008 to substantiate the opinion of Dr. Surmeier that Kv3.4 subunits were not important to the ability of neurons to spike at high frequency. Further in the declaration, Dr. Surmeier's submits that Parkinson's disease is based on the ability of Kv3.4 subunits to modify the efficiency of Kv3

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channels to promote fast spiking in neurons and one would not been able to predict that Kv3.4 subunits were important or relevant to the fast spiking neurons. Dr. Surmeier's conclusions about the state of the art regarding Kv3.4 is not convincing and does not discuss the findings of his work along with Tkatch et al., in recognizing the role of Kv3.4 channels in regulating the burst firing in fast spiking neurons and does not discuss how the results of Tkatch et al. would not specifically lead one of skill in the art to look to elucidating the role of the Kv3.4 potassium channel in diseases known to be associated aberrant high frequency discharging in neurons resulting which is thought to be critical in the emergence of Parkinson's disease.

With regard to Applicant's argument submitting the Examiner has not demonstrated a finite number of predictable solutions; because both Tkatch et al. and Weiser et al. teach Kv3.4 has been detected together in GP neurons with Kv3.1, Kv3.2, Kv3.3 in the KV3 family of potassium channels and because both Baranauskas et al. and Erisir et al. recognize the roles of KV3.1 and Kv3.2 in GP neurons, it would have been obvious to look to the other remaining potassium channels in this family, such as Kv3.4 to study the role this channel has in the progression of diseases, such as Parkinson's disease. Moreover, given Erisir et al. teach that blocking the expression of Kv3.1 and Kv3.2 leads to a decreased frequency of firing in fast spiking neurons, it would have been obvious to block the expression of Kv3.4 to determine the result on the firing rate of fast-spiking neurons, particularly given the suggestions by Tkatch et al. One would have a reasonable expectation of success at targeting a Kv3.4 gene given

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Weiser et al. teach the cDNA to said gene and Tuschl et al. teach the basic blue print on making and using siRNA to silence gene expression from any target gene of interest.

For these reasons, the rejection of record is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Thursday between 6 and 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Examiner
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